RAY Co., Ltd.
% Dave Yungvirt
CEO
Third Party Review Group, LLC
25 Independence Blvd
Warren, New Jersey 07059

May 21, 2025

Re: K251109
Trade/Device Name: SMARTDent
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: May 20, 2025
Received: May 20, 2025

Dear Dave Yungvirt:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251109

Device Name
SMARTDent

Indications for Use *(Describe)*
SMARTDent is intended for use as a software solution for managing dental diagnostic images and providing tools to support diagnosis.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K 251109 510(k) Summary

1. 510(k) Summary

The summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR Part 807.92.

2. Date: 20 May 2025

3. Administrative Information

Applicant		Ray Co., Ltd.
Address		1F~3F, 4F(Part), 5F, 265, Daeji-ro, Suji-gu, Yongin-si, 16882, Korea
Manufacturer	Name	Ray Co., Ltd.
	Address	1F~3F, 4F(Part), 5F, 265, Daeji-ro, Suji-gu, Yongin-si, 16882, Korea
	Tel	+82-31-605-1000
	Fax	+82-2-6280-5534
Contact Person	Name	Sooji Huh
	Email	sooji.huh@raymedical.co.kr

4. Device Information

Trade/Proprietary Name		SMARTDent
Common Name		Medical image management and processing system
Classification Name	Device	System, Image Processing, Radiological
	Regulation Number	21 CFR 892.2050
	Class	2
	Product Code	LLZ
	Review Panel	Radiology

5. Predicate device

Parameter	Predicate Device
Device Name	CS Imaging
Manufacturer	Carestream dental technology topco limited.
510(K) Number	K173622 Traditional 510k
Classification name	System, Image Processing, Radiological
Regulation number	21 CFR 892.2050
Primary product code	LLZ

6. Device Description

SMARTDent provides the function to efficiently manage CT, panorama, cephalometric, intraoral sensor images and intraoral camera images acquired using X-ray imaging equipment of Ray Co., Ltd. and performs various image analysis according to the diagnostic purposes.

7. Indication for use

SMARTDent is intended for use as a software solution for managing dental diagnostic images and providing tools to support diagnosis.

8. Intended Patient Population

- The patient population can be the possible person who can be taken X-ray diagnostic radiation exposure.
- There is no restriction for ethnic group, Sex, weight, health, or condition.
- We recommend patients for x-ray diagnostic radiation exposure to be over 5 years old.

9. Comparison with predicate device

The following table provides the summary of the technological characteristics of SMARTDent compared to the predicate device

Parameter	Proposed Device	Predicate Device
Manufacturer	RAY Co., Ltd.	Carestream dental technology topco limited.
Device name	SMARTDent	CS Imaging
510(K) Number	K251109 (Traditional 510K)	K173622 (Traditional 510K)

Common Name	Medical image management and processing system	Medical image management and processing system
Indications for use	SMARTDent is intended for use as a software solution for managing dental diagnostic images and providing tools to support diagnosis	CS Imaging is digital imaging software intended to be used with Carestream Dental's digital imaging devices by healthcare professionals to display, adjust, make measurement, print, export and store digital or digitized images to support image diagnosis in medical care, predominantly in dentistry
Image Input Sources	Intraoral system Extraoral system Intraoral digital video capture devices Intraoral scanners	Intraoral system Extraoral system Intraoral digital video capture devices Intraoral scanners
Image format	DICOM, JPEG, PNG, STL, PLY	DICOM, BMP, JPEG, TIFF, PNG, STL, PLY
Image Measurement Tools	line measurement multi-line measurement angle measurement Cobb's angle measurement	line measurement multi-line measurement angle measurement orthogonal measurement
Image viewing	single view multiple pop-up view layout view for 2D images layout view for CT images full mouth series(FMS) view pre-defined FMS	single view multiple pop-up view layout view for CT images full mouth series(FMS) view pre-defined FMS
Image manipulation	Brightness Contrast Gamma Sharpen Inverse	Brightness Contrast Gamma Sharpen Inverse
3D imagining capability	MPR view Cross-section view, Panoramic view, implant view TMJ view Nerve Implant simulation	MPR view Cross-section view, Panoramic view, implant view TMJ view Nerve Implant simulation Airway analysis
Image annotation	line, multi-line, free line, circle, ellipse, arrow, rectangle, text	line, multi-line, free line, spline, circle, ellipse, rectangle, landmark, arrow, text

User	The intended users of SMARTDent are health care professionals such as Oral health generalists, specialists and dental operator aides.	Used by health care professionals such as Oral health generalists, specialists and dental operator aides.
System Requirements	(2D recommend) CPU : Intel i5 2.0GHz (7th Gen.) or higher RAM : 8GB or higher Resolution : 1920 x 1080 Video Card : 512MB RAM OS : Windows 11 (3D View recommend) CPU : Intel Core i7-12700 RAM : 32GB of higher Resolution : 1920 x 1080 Video Card : NVidia GeForce GTX 4060, 8G OS : Windows 11	CPU: Intel Core i7-2600 RAM: 8 GB system RAM Resolution: 1280 x 1024, 32-bit color Graphic card: 1GB dedicated memory with open GL v3.2 support (AMD/ATI and Intel graphics chipset are NOT SUPPORTED) OS: Windows 10 64bit, Windows 11 64bit, Windows Server 2016/2019/2022 300 GB free disk space DVD RW drive Ethernet 100/1000 NIC

The product is principally just the same as in the previous 510(k) #K173622.
The complete of differences of the subject device to the predicate #K173622 device is as follows
- Image format
- System requirement

10. Performance Testing

Software, hardware, and integration verification and validation testing was performed in accordance with the FDA Guidance Document "Guidance for the Content of Premarket Submissions for Device Software Functions".

The validation suite includes validation of implemented mitigations related to device hazards identified in the risk management procedures.

All test results have been reviewed and approved, showing the SMARTDent to be substantially equivalent to the predicate devices.

11. Clinical Testing

Clinical testing is not a requirement and has not been performed.

12. Conclusions

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification. Ray Co., Ltd. concludes that the newly SMARTDent is safe, effective and substantially equivalent to the predicate device as described herein.